IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. NOVEN PHARMACEUTICALS, INC., Defendant.	Case No. 1:13-cv-00527-RGA Case No. 1:14-cv-00111-RGA [redacted] PUBLIC VERSION DATE FILED: November 25, 2014

PROPOSED JOINT PRETRIAL ORDER

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
McCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com

Of Counsel:

Nicholas N. Kallas
Charlotte Jacobsen
Dominick A. Conde
Christopher E. Loh
Daniel J. Minion
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

Attorneys for Plaintiffs

Dated: November 18, 2014

John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgslaw.com
mch@pgslaw.com

Of Counsel:

Steven J. Lee
Richard L. Delucia
Michael K. Levy
Chris J. Coulson
KENYON & KENYON LLP
One Broadway
New York, NY 10004
Tel: (212) 425-7200
Fax: (212) 425-5288

Attorneys for Defendant

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I. Nature Of The Case And Pleadings

1. This is a consolidated patent infringement case arising under the patent laws of the United States, Title 35, Section 271, based on Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking to commercially manufacture, use and sell generic rivastigmine transdermal systems (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths) (the "ANDA Products").

2. Plaintiffs are Novartis Pharmaceuticals Corporation ("NPC"), Novartis AG, Novartis Pharma AG and Novartis International Pharmaceutical Ltd. (collectively, "Novartis") and LTS Lohmann Therapie-Systeme AG ("LTS") (together with Novartis, "Plaintiffs"). Plaintiffs are represented by Daniel Silver of McCarter & English LLP and Nicholas N. Kallas, Charlotte Jacobsen, Dominick A. Conde, Christopher E. Loh, and Daniel J. Minion of Fitzpatrick, Cella, Harper & Scinto.

3. LTS makes and NPC sells in the United States Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), a transdermal patch drug product approved by the FDA for the treatment of dementia associated with Alzheimer's and Parkinson's diseases.

4. Plaintiffs listed United States Patents Nos. 6,335,031 ("'031 Patent") and 6,316,023 ("'023 Patent"), which are jointly owned by Novartis AG and LTS, in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for the Exelon® Patch.

5. Defendant is Noven Pharmaceuticals, Inc. ("Noven"). Noven is represented by John C. Phillips, Jr. and Megan C. Haney of Phillips, Goldman & Spence, P.A. and Steven J. Lee, Richard L. DeLucia, Michael K. Levy, and Chris J. Coulson of Kenyon & Kenyon LLP.

A. Civil Action No. 13-527-RGA

6. Noven filed Abbreviated New Drug Application [redacted] with the FDA, seeking approval to commercially manufacture, use and sell a rivastigmine transdermal system in 4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths, prior to the expiration of the '031 and '023 Patents.

7. On or about [redacted] Plaintiffs received a letter, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV letter"), notifying Plaintiffs that Noven had submitted an ANDA to the FDA seeking approval to commercially manufacture, use and sell Noven's 4.6 mg/24 hr and 9.5 mg/24 hr dosage strength ANDA Products, and advising Plaintiffs that the ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications") for the '031 and '023 Patents.

8. On April 3, 2013, Plaintiffs filed a Complaint alleging that the filing of the ANDA by Noven and the commercial manufacture, use, or sale of Noven's 4.6 mg/24 hr and 9.5 mg/24 hr dosage strength ANDA Products prior to the expiration of the '031 and '023 Patents constitute acts of infringement.[1] (C.A. No. 13-527-RGA, D.I. 1.)

9. On April 23, 2013, Noven filed its Answer, denying infringement of the '031 and '023 Patents and alleging that the claims of the '031 and '023 Patents are invalid. (C.A. No. 13-527-RGA, D.I. 12.) Noven did not file any counterclaims.

10. On June 12, 2013, the suit against Noven was consolidated with a suit against Alvogen Pine Brook, Inc. and Alvogen Group, Inc. (collectively "Alvogen Defendants")

[1] Plaintiffs' Complaint also alleged infringement by Noven Therapeutics, LLC ("Noven Therapeutics") and Hisamitsu Pharmaceutical Co., Inc. ("Hisamitsu"), but Plaintiffs' Complaint as to those parties was dismissed without prejudice, and Noven Therapeutics and Hisamitsu stipulated to be bound by an judgment, order, injunction, or decision entered in this action, or any appeal thereof, relating to the alleged infringement, validity, or enforceability of the '031 and '023 Patents, as if either were a named defendant. (C.A. No. 13-527-RGA, D.I. 1, D.I. 11.)

by the Court under Civil Action No. 13-52-RGA for claim construction proceedings, and the two actions were placed on the same schedule for expert discovery and trial. (C.A. No. 13-527-RGA, D.I. 26.)

11. On April 3, 2014, the Court held a Markman hearing, and on April 7, 2014, the Court issued a claim construction order. (C.A. No. 13-527-RGA, D.I. 107.)

12. On July 7, 2014, the suit against the Alvogen Defendants was dismissed. (C.A. No. 13-52-RGA, D.I. 180.) The Court entered final judgment of non-infringement in favor of Alvogen and against Plaintiffs as to Plaintiffs' claims relating to the 4.6 mg/24 hr and 9.5 mg/24 hr dosage strength rivastigmine transdermal products described in Alvogen's ANDA No. 204403. (*Id*. at D.I. 179 at 2.)

13. On October 20, 2014, the Court entered an order dismissing Plaintiffs' infringement claims against Noven as to the '023 Patent, provided that in all cases, Noven's ANDA Products conform to the specification, as set forth in Noven's [redacted] amendment to ANDA [redacted] (C.A. No. 13-527-RGA, D.I. 137.)

B. <u>Civil Action No. 14-111-RGA</u>

14. [redacted] Plaintiffs received a Paragraph IV letter, notifying Plaintiffs that Noven had submitted an amendment to its ANDA to the FDA seeking approval to make and sell Noven's 13.3 mg/24 hr dosage strength ANDA Product, and advising Plaintiffs that the ANDA included Paragraph IV certifications for the '031 and '023 Patents.

15. On January 30, 2014, Plaintiffs filed a Complaint alleging that Noven's filing of its ANDA and the commercial manufacture, use, or sale of Noven's 13.3 mg/24 hr

dosage strength ANDA Product prior to the expiration of the '031 and '023 Patents constitute acts of infringement.[2] (C.A. No. 14-111, D.I. 1.)

16. On March 12, 2014, Noven filed its Answer, denying infringement of the '031 and '023 Patents and alleging that the claims of the '031 and '023 Patents are invalid. (C.A. No. 14-111, D.I. 11.) Noven did not file any counterclaims.

C. The Consolidated Action

17. On April 11, 2014, Civil Action No. 14-111-RGA was consolidated with Civil Action No. 13-527, for all purposes including trial. (C.A. No. 14-111, D.I. 17.)

18. All non-liability issues have been bifurcated. (C.A. No. 13-527, D.I. 26; C.A. No. 14-111, D.I. 19.) Plaintiffs have not currently asserted willful infringement in this consolidated action, or that this is an exceptional case, but reserve the right to do so should circumstances warrant.

D. Related Civil Action Nos. 11-cv-1112-RGA, 13-cv-317, 11-1077-RGA, And 13-1467-RGA

19. In Plaintiffs' patent infringement case against Watson Laboratories, Inc. et al. ("Watson") (District of Delaware, C.A. Nos. 11-cv-1112-RGA & 13-cv-371-RGA), the Court entered final judgment finding that the rivastigmine transdermal products containing BHT, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, that are the subject of Watson's ANDA No. 202119, infringe claims 3, 7, 13, 16, and 18 of the '031 Patent and claims 2 and 7 of

[2] Plaintiffs' Complaint also alleged infringement by Noven Therapeutics and Hisamitsu, but Plaintiffs' Complaint as to those parties was dismissed without prejudice, and Noven Therapeutics and Hisamitsu stipulated to be bound by an judgment, order, injunction, or decision entered in this action, or any appeal thereof, relating to the alleged infringement, validity, or enforceability of the '031 and '023 Patents, as if either were a named defendant. (C.A. No. 14-111-RGA, D.I. 1, D.I. 10.)

the '023 Patent and that those claims are not invalid and not obvious. (C.A. No. 11-cv-1112-RGA, D.I. 45; C.A. No. 13-cv-371-RGA, D.I. 24.)

20. In Plaintiffs' patent infringement case against Par Pharmaceutical, Inc. ("Par") (District of Delaware, Consolidated C.A. Nos._11-cv-1077-RGA & 13-cv-1467-RGA) and Par's declaratory judgment case against Plaintiffs (District of Delaware, C.A. No. 14-cv-843-RGA), the Court entered final judgment finding that the rivastigmine transdermal products, 4.6 mg/24, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, that are the subject of Par's ANDA [redacted] do not infringe the '031 or '023 Patents, that claim 7 of the '031 Patent is not invalid, and that claims 3, 7, 13, 16, and 18 of the '031 Patent and claims 2 and 7 of the '023 Patent are not obvious. (C.A. No. 11-cv-1077-RGA, D.I. 429; C.A. No. 13-cv-1467-RGA, D.I. 86; C.A. No. 14-cv-843-RGA, D.I. 29.)

II. Jurisdiction

21. This action arises under the patent laws of the United States. This Court has jurisdiction over the '031 Patent with respect to Noven's 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strength ANDA Products under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

III. Admitted Facts

22. The parties stipulate to the facts listed in attached **Exhibit 1**. These stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

IV. Disputed Facts

23. Plaintiffs' statement of disputed facts is attached at **Exhibit 2**.

24. Noven's statement of disputed facts is attached as **Exhibit 3**.

V. Issues Of Law

25. Plaintiffs' statement of issues of law is attached as **Exhibit 4**.

26. Noven's statement of issues of law is attached as **Exhibit 5**.

VI. Exhibits

27. The list of exhibits which, subject to continued meeting and conferring in advance of and during trial, may ultimately be offered jointly by Plaintiffs and Noven, is attached as **Exhibit 6**. This list includes the parties' respective objections for the Court's consideration in the event the parties are unable to reach agreement on introducing them jointly.

28. The list of exhibits which may be offered by Plaintiffs, including Noven's objections thereto, is attached as **Exhibit 7**.

29. The list of exhibits which may be offered by Noven, including Plaintiffs' objections thereto, is attached as **Exhibit 8**.

30. Plaintiffs and Noven reserve the right to offer exhibits set forth on the other side's exhibit list, even if not set forth on their own exhibit list. All objections to such exhibits are preserved, regardless of whether such exhibits also appear on the objecting party's exhibit list.

31. Exhibits to be used solely for impeachment or cross-examination need not be included on the lists of trial exhibits. To be admitted into evidence, exhibits used for impeachment and/or cross-examination must also be included on the lists of trial exhibits.

32. Except as otherwise set forth herein, any document not listed in Exhibits 6 to 8 above, will be precluded from trial, absent good cause shown.

33. Any document shall be deemed to be authentic absent a specific objection set forth in an exhibit list challenging that document's authenticity. Any document that on its face appears to have been authored by an employee, officer, or agent of a party shall be deemed to be *prima facie* authentic, subject to the right of any party against whom such a document is offered to adduce evidence to the contrary or to require that the offering party provide

authenticating evidence if the opposing party has a reasonable basis to believe the document is not authentic. Any document that on its face appears to be a newspaper, periodical, article, journal, patent, patent publication, or other publication or portion thereof shall be deemed to be *prima facie* authentic, subject to the right of any party against whom such a document is offered to adduce evidence to the contrary or to require that the offering party provide authenticating evidence if the opposing party has a reasonable basis to believe the document is not authentic.

34. Legible copies of documents may be offered and received in evidence to the same extent as an original.

35. The demonstrative exhibits the parties intend to use at trial do not need to be described on their respective lists of trial exhibits.

36. Plaintiffs shall be permitted an opening argument at the start of the trial. Noven shall be permitted an opening argument following Plaintiffs' opening argument. The sides shall exchange by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered) lists of any exhibits and copies of any demonstrative exhibits (except for demonstrative exhibits that will be created live in the courtroom) that each party intends to use in its opening argument by 1:00 PM EDT on November 30, 2014.

37. The party that bears the burden of proof on an issue at trial shall produce to the opposing party by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered) the following materials with respect to that issue by 7:00PM EDT three calendar days before such materials are to be used at trial:

a. A list of the witnesses that the party will call to testify live or by deposition/trial designation on that day, in the order that they will be called;

b. A list of the exhibits that the party will use during the direct examination of each witness identified by exhibit number;

c. A copy of each demonstrative exhibit that the party will use during the direct examination of each witness (except for demonstrative exhibits that will be created live in the courtroom);

d. A list of the specific deposition or trial designations, by line and page number, of each deposition/trial transcript that the party will use that day, including an identification of whether the designations will be played by video or read into the record; and

e. A good faith estimate of when the party intends to conclude its case-in-chief.

A party in receipt of the above materials shall inform the producing party of any objections to those materials and provide any deposition counter-designations by 7:00PM EDT two calendar days before such materials are to be used at trial. The parties shall meet and confer to resolve those objections before trial resumes on the day such materials are to be used at trial.

38. The party that must rebut an issue at trial shall produce to the opposing party by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered) the following materials with respect to that issue by 7:00PM EDT two calendar days before such materials are to be used at trial:

a. A list of the rebuttal witnesses that the party will call to testify live or by deposition/trial designation on that day, in the order that they will be called;

b. A list of the exhibits that the party will use during the direct examination of each rebuttal witness identified by exhibit number;

c. A copy of each demonstrative exhibit that the party will use during the direct examination of each rebuttal witness (except for demonstrative exhibits that will be created live in the courtroom); and

d. A list of the specific rebuttal deposition or trial designations, by line and page number, of each deposition/trial transcript that the party will use that day, including an identification of whether the designations will be played by video, or read into the record.

A party in receipt of the above materials shall inform the producing party of any objections to those materials and provide any deposition counter-designations by 7:00PM EDT one calendar day before such materials are to be used at trial. The parties shall meet and confer to resolve those objections before trial resumes on the following day.

39. Each demonstrative exhibit shall disclose to the other side on the face of the demonstrative exhibit all trial exhibits that form the basis of the demonstrative exhibit.

40. Demonstratives to be used on cross-examination are not required to be provided to the other side in advance.

41. Exhibits to be used solely for impeachment or cross-examination need not be disclosed in advance of being used or offered at trial. Exhibits used for cross-examination and/or impeachment may only be admitted into evidence subject to the Federal Rules of Evidence or other applicable principles of law. To be admitted into evidence, exhibits used for cross-examination and/or impeachment must also be identified in advance in accordance with ¶¶ 27 to 29 above and produced to the opposing party by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered) by 5:30 PM EDT the day before they are used.

VII. Witnesses

42. Plaintiffs' list of witnesses they may call at trial and deposition designations, along with Noven's objections thereto and counter-designations, is attached as **Exhibit 9**.

43. Noven's list of witnesses it may call at trial and deposition designations, along with Plaintiffs' objections thereto and counter-designations, is attached as **Exhibit 10**.

44. Any witness not listed in Exhibits 9 to 10 above will be precluded from trial absent good cause shown. Such good cause shall include testimony required to authenticate any documents subject to an authenticity objection.

45. For good cause shown, limited supplementation of deposition designations will be permitted through the close of trial unless the opposing party will be unfairly prejudiced by such supplementation. The opposing party shall have the right to counter-designate. Supplementation to designate testimony for purposes of identification or authentication of a document shall satisfy the requirement of good cause.

46. To the extent that deposition designations or counter-designations are admitted into evidence, they must either be played by video or read in open court. If a party opts

to introduce deposition testimony, any counter-designation of that same witnesses' testimony must be submitted in the same medium, and the testimony designated by both sides will be played or read consecutively in the sequence in which the testimony was originally given at deposition. To the extent deposition designations are read or played in open court, each side will be charged the time taken to read or play its designations, as measured by the proportion of the number of lines of testimony for its designations to the total number of lines of testimony read or played.

47. Plaintiffs and Noven each reserve the right to offer deposition testimony designated by the other side (whether as a designation or a counter-designation) even if not separately listed on their own deposition designation list, subject to any evidentiary objections.

48. Any deposition testimony to be used at trial may be used whether or not the transcripts of such deposition have been signed and filed.

49. The listing of a deposition designation does not constitute an admission as to the admissibility of the testimony nor is it a waiver of any applicable objection.

VIII. Brief Statement Of Intended Proofs

50. In support of their claims and in addition to the facts not in dispute, Plaintiffs expect to offer the proofs set forth in **Exhibit 11**.

51. In support of their claims and in addition to the facts not in dispute, Noven expects to offer the proofs set forth in **Exhibit 12**.

IX. In Limine Motions

52. Plaintiffs' *in limine* motions, along with Noven's oppositions thereto and Plaintiffs' reply, are set forth in **Exhibit 13**.

53. Noven's *in limine* motions, along with Plaintiffs' oppositions thereto and Noven's reply, are set forth in **Exhibit 14**.

X. Certification Of Settlement Discussions

54. The parties certify that they have engaged in a good faith effort to explore the resolution of the controversy by settlement. A settlement has not yet been reached.

XI. Miscellaneous Issues

A. Amendments Of The Pleadings

55. There are no proposed amendments of the pleadings.

B. Damages

56. The parties do not intend to seek damages at this time, except all parties reserve the right to seek attorneys' fees, costs and expenses pursuant to 35 U.S.C. § 285. Plaintiffs reserve the right to seek damages if Noven manufactures, uses, sells, offers to sell, or imports any of the accused ANDA Products prior to the expiration date of the '031 Patent.

C. Expected Duration And Scope Of Trial

57. Trial is scheduled to begin on December 1, 2014 and to last three days. Fifty percent of the time (10.5 hours total) will be allotted to Plaintiffs and the remaining fifty percent (10.5 hours total) to Noven. Time that a party is presenting opening statements, objecting to evidence in open court, examining or cross-examining witnesses, presenting evidence by reading or playing a deposition transcript, or otherwise speaking or arguing on behalf of a party will be counted as the time of that party.

D. Type Of Trial

58. This is a non-jury trial.

E. Order Of Proof

59. The following order of proof will apply to the trial:

a. Opening arguments will be delivered in the following order: Plaintiffs, then Noven.

b. Plaintiffs then shall present their affirmative case on infringement against Noven.

c. Upon conclusion of Plaintiffs' testimony and evidence on infringement against Noven, Noven shall present its testimony and evidence relating to its allegations that it has not and will not infringe the '031 Patent.

d. Upon conclusion of the infringement issues in the case, Noven shall present its testimony and evidence that the '031 Patent is invalid.

e. Plaintiffs thereafter shall present their rebuttal case that the '031 Patent is valid upon completion of Noven's testimony and evidence on invalidity.

f. [**Noven's position:** Noven thereafter shall present a reply case upon the completion of Plaintiffs' rebuttal.] [**Plaintiffs' position:** Neither Plaintiffs nor Noven shall present a reply case upon the completion of the opposing side's rebuttal case. Plaintiffs submit that no reply is necessary because, pursuant to Federal Rules of Civil Procedure 26 and 37, each side's experts' testimony will be limited to the opinions set forth in their expert reports. However, if Noven is permitted to present a reply case with respect to invalidity, such reply case must comply with the Federal Rules of Civil Procedure, Federal Rules of Evidence, or other applicable

principles of law, and be limited to anything unexpected in Plaintiffs' rebuttal case on validity.]

F. Prior Testimony From Related Civil Actions

60. The parties "are permitted to rely on fact discovery developed in the related cases *Novartis v. Alvogen*, 13-cv-0052-RGA, *Novartis v. Noven*, 13-cv-0527-RGA, and *Novartis v. Par et al.*, 11-cv-1077-RGA," including prior deposition testimony from those related cases to the extent those witnesses do not testify at the present trial and to the extent such testimony has been designated in accordance with ¶¶ 37-38 and Section VII above. (C.A. No. 14-111-RGA, D.I. 19.) The parties shall also be permitted to rely on prior trial testimony of witnesses from the related civil actions in Section II.D above to the extent those witnesses do not testify at the present trial and such testimony has been designated and previously disclosed to the opposing party in accordance with Federal Rule of Civil Procedure 26 and ¶¶ 37-38 and Section VII above.

XII. Order To Control Course Of Action

61. This order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

Dated: November 18, 2014

/s/ Daniel M. Silver
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
McCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com

Of Counsel:

Nicholas N. Kallas
Charlotte Jacobsen
Dominick A. Conde
Christopher E. Loh
Daniel J. Minion
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

Attorneys for Plaintiffs

/s/ John C. Phillips, Jr.
John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgslaw.com
mch@pgslaw.com

Of Counsel:

Steven J. Lee
Richard L. Delucia
Michael K. Levy
Chris J. Coulson
KENYON & KENYON LLP
One Broadway
New York, NY 10004
Tel: (212) 425-7200
Fax: (212) 425-5288

Attorneys for Defendant

SO ORDERED:

Date: _____

_____
Hon. Richard G. Andrews
United States District Judge